REMARKS

Reconsideration of this Application and entry of these Amendments is respectfully requested. By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which they are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

In the claims

Claims 1-3, 6-16, 18-20, and 29 are pending in this application. Claims 1, 9, and 16 are currently amended. The amendments are supported, for example, by Example 1. No new matter has been added as a result of the present amendments.

Double Patenting Rejection

The Office provisionally rejects claims 1-3, 6-16, 18-20, and 29 as being unpatentable over claims 19, 27, and 34 of co-pending Application No. 12/256,665. Respectfully, Applicants elect to postpone responding until the rejection is no longer a "provisional" rejection.

Applicants believe the election to postpone a response is appropriate in view of the MPEP at 804(I)B which states,

> "The 'provisional' double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that 'provisional' double patenting rejection is the only rejection remaining in at least one of the applications."

35 U.S.C. §112 Rejections

The Office Action rejects claims 1-3, 6-16, 18-20, and 29 under 35 U.S.C. §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one of normal skill in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

With regard to "between about 105 and 260 units" the claim limitation is explicitly stated in Example 1 at paragraph 123.

With regard to "a pure botulinum type A or type B toxin" Applicants direct the Office's attention to paragraph 80 of the published application:

> [0080] A method according to our invention can be carried out by administration of a Clostridial toxin to a patient with a MOD. The Clostridial toxin used is preferably a botulinum toxin (as either a complex or as a pure [i.e. about 150 kDa molecule], such as a botulinum toxin A, B, C, D, E, F or G. Administration of the Clostridial toxin can be by a transdermal route (i.e. by application of a Clostridial toxin in a cream, patch or lotion vehicle), subdermal route (i.e. subcutaneous or intramuscular), or intradermal route of administration.

Applicants have also amended claims 1, 9, and 16 to specify multiple injection locations. The amendments are supported by Example 1 of the Specification.

Therefore, Applicants request that this rejection be withdrawn.

35 U.S.C. §103 Rejections

The Office Action rejects claims 1-3, 6-16, 18-20, and 29 under 35 U.S.C. §103(a) as being unpatentable over Bigal *et al*. (Cephalalgia, 2002, 22, p. 432-438; "Bigal") in view of Cephalalgia, An International Journal of Headache, Volume 24, Supplement 1, 2004 ("Cephalalgia") in view of Loder *et al*. (The Clinical Journal of Pain, 18:S169-S176, 2002; "Loder"). Applicants respectfully traverse this rejection.

As to the Appeal decision relating to Application Serial No. 11/039,506, the claims at issue in '506 specified administration of between about 1 and about 1500 units. Applicants note the pending claims specify injections of between about 105 and about 260 units.

Regarding Loder, the Office directs Applicants to page S172, Figure 1 as support for the Office's assertion that the reference teaches or suggests the claimed dosage amounts. Applicants disagree, and cite the same Figure 1:

for botulinum toxin type A, 25-100 units are generally used, divided among the injection sites

Thus, Loder teaches an upper limit of 100 units, not injections of between 25 and 100 units. Additionally, the claimed dosages of between about 105 and about 260 units are well above that amount described in Loder as no better than the placebo. Thus, rather than suggesting the method of the pending claims, Loder teaches away by describing the positive effects of 25-unit treatments while labeling the 75-unit treatments as ineffective. It is significant that the dosage specified by the pending claims is considerably higher than that described in Loder, as one of skill in the art would not find a positive result at 25 units combined with no results at 75 units to suggest treatments of greater than 105 units, especially in the case of neurotoxins.

Therefore, Applicants respectfully ask that the rejection be withdrawn.

Conclusion

For the foregoing reasons, Applicants believe all the pending claims are in condition for allowance and a Notice of Allowance to that effect is respectfully requested. The Commissioner is hereby authorized to charge any additional fees which may be required for entry of this paper, or credit any overpayment, to Deposit Account No. 01-0885. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, the Examiner is kindly urged to call the undersigned at telephone number (714) 246-6458.

Respectfully submitted,

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